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Indian Standard

IMPLANTS FOR SURGERY—STAPLES WITH PARALLEL LEGS FOR ORTHOPAEDIC USE — GENERAL REQUIREMENTS

ICS 616-089.23:621.886.3

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NEW DELHI 110002

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Price Group 3

Orthopaedic Instruments and Accessories Sectional Committee, MHD 2

NATIONAL FOREWORD

This Indian Standard which is identical with ISO 8827 : 1988 'Implants for surgery — Staples with parallel legs for orthopaedic use — General requirements', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on the recommendation of the Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist.

The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 5832-1 : 1987	IS 5347 (Part 2) : 1993 Requirements for orthopaedic implants: Part 2 Wrought stainless steel (*first revision*)	Identical
ISO 5832-3 : 1978	IS 5347 (Part 4) : 1984 Requirements for orthopaedic implants: Part 4 Wrought titanium 6-aluminium 4-vanadium alloy	Identical
ISO 5832-4 : 1978	IS 5347 (Part 5) : 1984 Requirements for orthopaedic implants: Part 5 Cobalt-chromium-molybdenum casting alloys	Identical
ISO 5832-5 : 1978	IS 5347 (Part 6) : 1984 Requirements for orthopaedic implants: Part 6 Wrought-cobalt-chromium-tungsten nickel alloy	Identical
ISO 6018 : 1987	IS 14240 : 1995 Orthopaedic implants — General requirements for marking, packaging and labelling	Identical
ISO 6892 : 1984	IS 1608 : 1972 Method for tensile testing of steel products (*first revision*)	Technically equivalent

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

IMPLANTS FOR SURGERY—STAPLES WITH PARALLEL LEGS FOR ORTHOPAEDIC USE — GENERAL REQUIREMENTS

1 Scope and field of application

This International Standard covers general requirements and the designation of dimensions and tolerances of staples with parallel legs intended for use in orthopaedic surgery.

NOTE — The annex gives guidance on the selection and use of staples and does not form an integral part of this International Standard.

2 References

ISO 5832, *Implants for surgery — Metallic materials —*

Part 1: Wrought stainless steel.

Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.

Part 4: Cobalt-chromium-molybdenum casting alloy.

Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.

ISO 6018, *Implants for surgery — General requirements for marking, packaging and labelling.*

ISO 6892, *Metallic materials — Tensile testing.*

3 Design

3.1 Radius of curvature

The internal radius of curvature of staples made from wire shall be not less than 2 mm or the diameter of the wire, whichever is the greater. The curve shall have a smooth contour.

3.2 Points

Points of staples shall be conical, trocar-shaped, spear-shaped or flattened (i.e tapered in one plane).

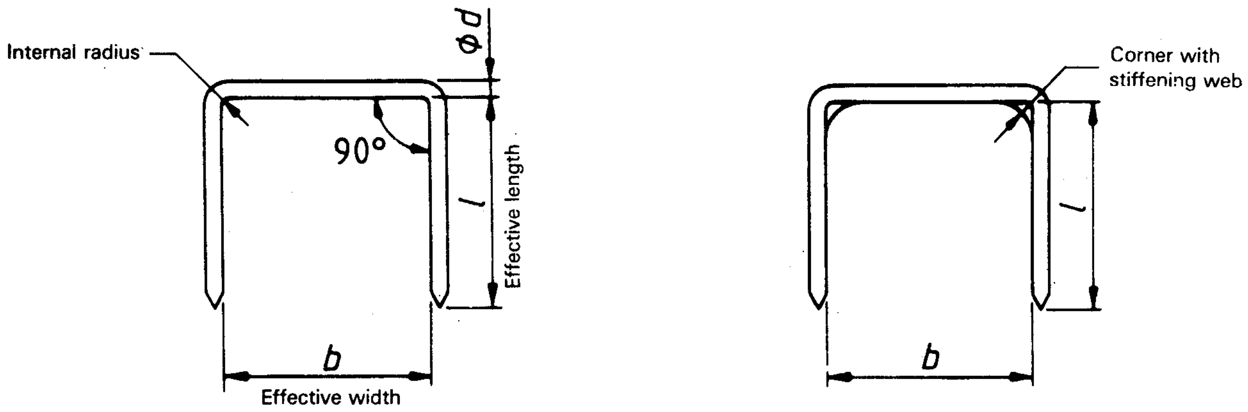
3.3 Legs

The legs shall be parallel.

NOTES

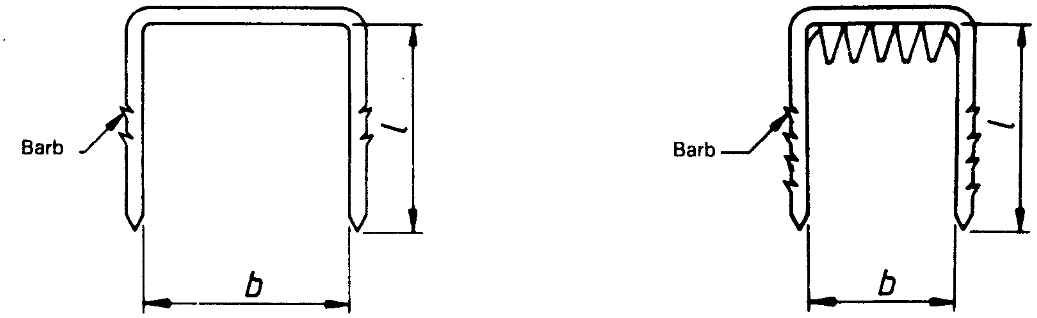
1 Examples of typical forms of staples used in orthopaedic surgery are illustrated in figure 1. Figure 1 shows the designation of dimensions and gives nomenclature; it does not purport to specify design requirements and does not otherwise form part of the requirements for staples as laid down in this International Standard.

2 Staples are commonly of circular, oval or modified rectangular cross-section, although other forms may be used. If staples are made from wire, wire 2,5 mm in diameter is commonly used. Greater strength may be achieved by using an oval cross-section, generally of the order of 4 mm x 2 mm, or by reinforcing the bend area with webs [see figure 1b)]. The legs may be plain, or have barbs or other surface features or treatments.



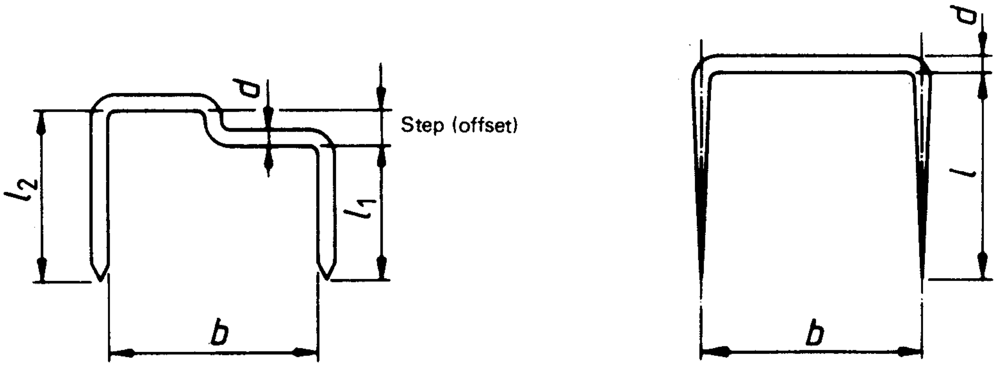
a) **Standard staple**

b) **Webbed staple**



c) **Barbed staple**

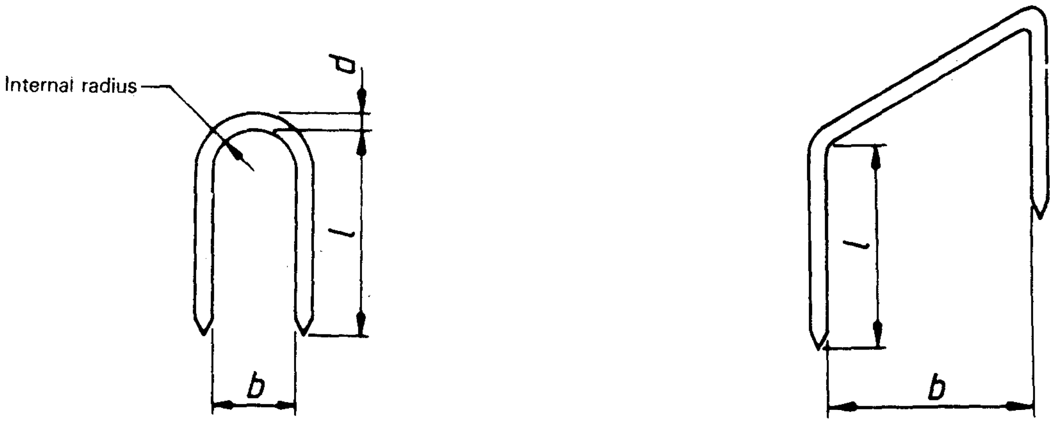
d) **Barbed and webbed staple**



e) **Stepped (offset) staple**

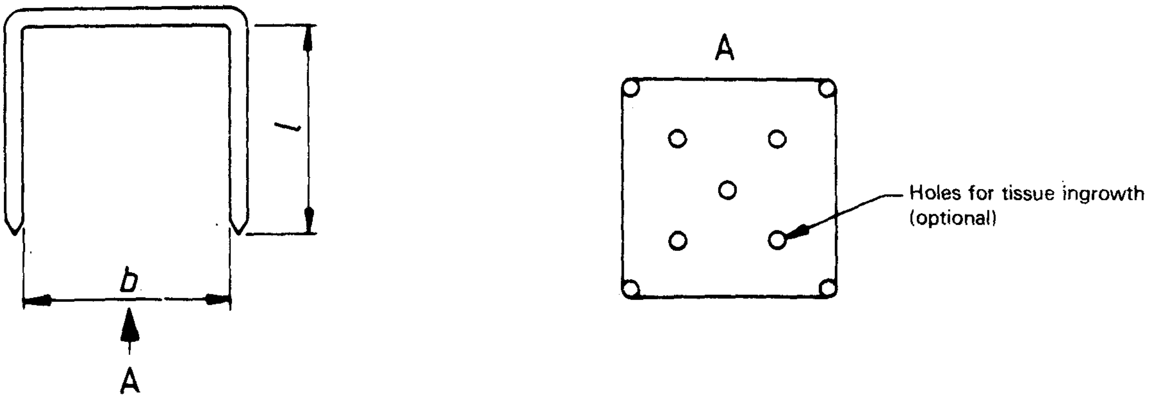
f) **Tapered staple**

Figure 1 — Examples of typical forms of staples for use in orthopaedic surgery



g) **Common staple**

h) **Oblique staple**



i) **Table staple**

NOTE — The figures illustrate various types of staple for the purpose of defining the relevant dimensions and features, but the illustrations do not otherwise form part of the requirements for staples as laid down in this International Standard.

Figure 1 — Examples of typical forms of staples for use in orthopaedic surgery (*concluded*)

4 Size designation

The size of staples shall be designated by effective length, *l*, effective width, *b*, and diameter, *d*, respectively (see figure 1), expressed in millimetres, as follows:

25 × 20 × 1

Staples with legs of unequal length shall have the effective length of each leg stated.

Staples of oval or modified rectangular cross-section shall have the major and minor cross-sectional dimensions stated.

5 Tolerances

The effective length and effective width of staples shall be in accordance with the nominal dimensions ± 1 mm.

The axis of one leg of the staple shall be parallel, with respect to the axis of the other leg, within a cylindrical tolerance zone 0,5 mm in diameter (see figure 2).

In the case of table staples [see figure 1i)], the parallelism tolerances shall apply to each and every pair of legs.

6 Materials

6.1 General

Staples shall be made from austenitic stainless steel, cast cobalt-chromium-molybdenum alloy, wrought cobalt-chromium-tungsten-nickel alloy, or wrought titanium alloy. When produced from wire or by casting, the material shall satisfy the requirements laid down in 6.2, 6.3, 6.4 and 6.5.

6.2 Austenitic stainless steel wire

6.2.1 Composition

Wire used in the manufacture of staples shall be made from austenitic stainless steel in accordance with ISO 5832-1 and shall comply with the requirements of the corrosion resistance test specified in ISO 5832-1.

Tolerance in millimetres

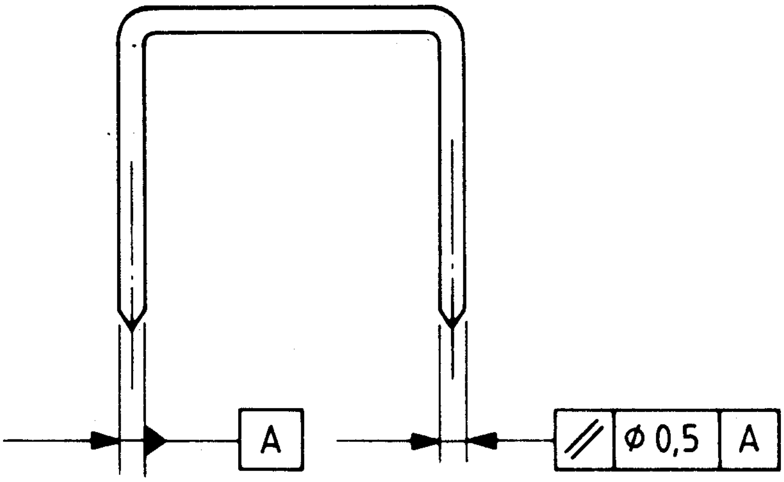


Figure 2 — Parallelism of legs

6.2.2 Tensile properties

When tested in accordance with ISO 6892, the tensile properties of the wire in the as-drawn (coiled) condition and after straightening shall be as given in the table.

Table — Tensile properties of wire made from austenitic stainless steel

Diameter	Minimum tensile strength		Percentage elongation after fracture min.
	As-drawn (coiled) condition	Straightened condition	
mm	N/mm^2	N/mm^2	%
1	1 550	1 400	3
1,6	1 550	1 400	3
2	1 550	1 400	3
2,5	1 550	1 400	3
3,15	1 400	1 325	5
4	1 400	1 240	5

NOTE — The wire may have been subjected to a stress-relieving heat treatment at a temperature not exceeding 450 °C.

6.3 Cast cobalt-chromium-molybdenum alloy

6.3.1 Composition

Cast cobalt-chromium-molybdenum alloy used in the manufacture of staples shall comply with the requirements laid down in ISO 5832-4, except for the tensile properties of the material which shall comply with the requirements laid down in 6.3.2.

6.3.2 Tensile properties

When tested in accordance with ISO 6892, the tensile strength of the staples in the as-cast condition shall be not less than 700 N/mm^2, the proof stress of non-proportional elongation $R_{p0,2}$ shall be not less than 500 N/mm^2 and the percentage elongation after fracture shall be not less than 8 %.

6.4 Wrought cobalt-chromium-tungsten-nickel alloy

6.4.1 Composition

Wrought cobalt-chromium-tungsten-nickel alloy used in the manufacture of staples shall comply with the requirements laid down in ISO 5832-5, except for the tensile properties of the material which shall comply with the requirements laid down in 6.4.2.

6.4.2 Tensile properties

When tested in accordance with ISO 6892, the tensile strength of the cold drawn wire used for staples shall be not less than 1 280 N/mm^2 and the percentage elongation after fracture shall be not less than 7 %.

6.5 Wrought titanium alloy

6.5.1 Composition

Wire made of wrought titanium 6-aluminium 4-vanadium alloy shall comply with the requirements laid down in ISO 5832-3, except for the tensile properties of the material which shall comply with the requirements laid down in 6.5.2.

6.5.2 Tensile properties

When tested in accordance with ISO 6892, the tensile strength of the wires used for staples shall be within the range from 1 150 N/mm^2 to 1 400 N/mm^2 and the percentage elongation after fracture shall be not less than 3 %.

7 Finish

The surface finish shall be free from burrs, scratches and other defects visible to the naked eye.

NOTE — Particular care should be taken with regard to the quality of the surface finish of the curved portions of staples.

8 Packaging

Packaging shall be in accordance with ISO 6018.

9 Marking of packages

Packages shall be marked in accordance with ISO 6018. The size of the staples shall be marked in accordance with clause 4 of this International Standard.

Annex

Guidance on use and selection of staples

(This annex does not form an integral part of the Standard.)

In clinical practice, these devices may be found to break or open out under load. This tendency may be reduced by selecting staples

a) of larger cross-sectional area;

b) with webs as illustrated in figures 1b) and 1d);

c) made by casting in cobalt-chromium-molybdenum alloy or by forging in other suitable alloys.

Extra strength is most important when staples are used for epiphyseal arrest, when the number and location of the staples needs special consideration in order to distribute the load. The staples should be inserted with the legs of the staple parallel to the epiphyseal cartilage plate; oblique or stepped (offset) staples are intended to facilitate this where the bone surface is flared.

In order to obtain improved holding, optional surface features, such as barbs or coatings, may be added. The legs of the staple should not be weakened by incorporating these features which may themselves cause problems when the staples are removed at a later stage.

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